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*Attorneys for Plaintiffs Bayer Schering Pharma AG and Bayer
HealthCare Pharmaceuticals Inc.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA**

BAYER SCHERING PHARMA AG &
BAYER HEALTHCARE
PHARMACEUTICALS INC.

Plaintiffs,

v.

SUN PHARMACEUTICAL INDUSTRIES
LIMITED, SUN PHARMA GLOBAL FZE,
SUN PHARMA GLOBAL, & SUN
PHARMACEUTICAL INDUSTRIES, INC.

Defendants.

COMPLAINT

JURY TRIAL

1 Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc.
2 (collectively “Bayer”) bring this Complaint for patent infringement against Defendants Sun
3 Pharmaceutical Industries Ltd., Sun Pharma Global FZE, Sun Pharma Global, & Sun
4 Pharmaceutical Industries, Inc. (collectively “Sun”) and allege as follows:

5 **PARTIES**

6 1. Plaintiff Bayer Schering Pharma AG (“Bayer Schering”), formerly known as
7 Schering AG, is a corporation organized and existing under the laws of the Federal Republic of
8 Germany, having a principal place of business in Müllerstrasse 178, 13353 Berlin, Germany.

9 2. Plaintiff Bayer HealthCare Pharmaceuticals Inc. (“Bayer HealthCare”), formerly
10 known as Berlex, Inc., is a corporation organized and existing under the laws of the State of
11 Delaware, having a principal place of business at 6 West Belt, Wayne, New Jersey 07470.

12 3. On information and belief, Sun Pharmaceutical Industries Limited is an Indian
13 corporation having a place of business at Acme Plaza, Andheri-Kurla Road, Andheri (East),
14 Mumbai-400 059, India. On information and belief, Sun Pharmaceutical Industries Limited is in
15 the business of, among other things, manufacturing and selling generic copies of branded
16 pharmaceutical products through various operating subsidiaries, including Sun Pharma Global,
17 Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc.

18 4. On information and belief, Sun Pharma Global is a corporation organized under
19 the laws of the British Virgin Islands having a post-office box at International Trust Building,
20 P.O. Box No. 659, Road Town, Tortola, British Virgin Islands. On information and belief, Sun
21 Pharma Global is in the business of, among other things, manufacturing and selling generic
22 copies of branded pharmaceutical products for the United States market through various operating
23 subsidiaries, including Sun Pharma Global FZE. Sun Pharma Global is a wholly owned
24 subsidiary and alter ego of Sun Pharmaceutical Industries Limited.

25 5. On information and belief, Sun Pharma Global FZE is a corporation organized
26 under the laws of the United Arab Emirates having a place of business at United Arab Emirates
27 with a principal place of business at Executive Suite # 43, Block-Y, SAIF Zone, PO Box 122304,
28 Sharjah, U.A.E. On information and belief, Sun Pharma Global FZE is in the business of, among

1 other things, manufacturing and selling generic copies of branded pharmaceutical products
2 throughout the United States including within the State of Nevada. Sun Pharma Global FZE is a
3 wholly owned subsidiary and alter ego of Sun Pharma Global.

4 6. On information and belief, Sun Pharmaceutical Industries, Inc. is a corporation
5 organized under the laws of the State of Michigan with headquarters at 29714 Orion Ct.,
6 Farmington Hills, MI 48334 and having its principal place of business at 270 Prospect Plains
7 Road, Cranbury, NJ 08512. On information and belief, Sun Pharmaceutical Industries, Inc. is in
8 the business of, among other things, manufacturing and selling generic copies of branded
9 pharmaceutical products throughout the United States including within the State of Nevada. Sun
10 Pharmaceutical Industries, Inc. is a wholly owned subsidiary and alter ego of Sun Pharmaceutical
11 Industries Limited.

12 7. On information and belief and consistent with their practice with respect to other
13 generic products, following any FDA approval of an Abbreviated New Drug Application
14 (“ANDA”), Sun Pharmaceutical Industries Limited, Sun Pharma Global FZE, Sun Pharma
15 Global, & Sun Pharmaceutical Industries, Inc. will act in concert to distribute and sell Sun’s oral-
16 contraceptive products for ANDA No. 20-2318 throughout the United States, including within
17 Nevada. On information and belief, Sun Pharmaceutical Industries Ltd., Sun Pharma Global
18 FZE, Sun Pharma Global, & Sun Pharmaceutical Industries, Inc. know and intend that Sun’s
19 ANDA product for ANDA No. 20-2318 will be distributed and sold in the United States,
20 including within Nevada.

21 8. On information and belief, and consistent with their practice with respect to other
22 generic products, Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, Sun Pharma
23 Global, & Sun Pharmaceutical Industries, Inc. acted in concert to prepare and submit ANDA No.
24 20-2318. On information and belief, Sun Pharmaceutical Industries Ltd., Sun Pharma Global
25 FZE, Sun Pharma Global, & Sun Pharmaceutical Industries, Inc. actively participated in the
26 preparation of ANDA No. 20-2318 and these entities caused the submission of this ANDA to the
27 FDA. On information and belief, Sun Pharma Global FZE acted as the agent of Sun
28 Pharmaceutical Industries Ltd., Sun Pharma Global, & Sun Pharmaceutical Industries, Inc. in

1 submitting ANDA No. 20-2318 to the FDA.

2 3 **JURISDICTION AND VENUE**

4 9. This action arises under the patent laws of the United States of America. This
5 Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

6 10. On information and belief, Sun Pharmaceutical Industries Limited is subject to
7 personal jurisdiction in the State of Nevada because, among other things, Sun Pharmaceutical
8 Industries Limited, itself and through its wholly-owned and operating subsidiaries Sun Pharma
9 Global FZE, Sun Pharma Global, and Sun Pharmaceutical Industries, Inc., has purposely availed
10 itself of the benefits and protections of Nevada's laws such that it should reasonably anticipate
11 being haled into court here. On information and belief, Sun Pharmaceutical Industries Limited,
12 itself and through its wholly owned and operating subsidiaries Sun Pharma Global FZE, Sun
13 Pharma Global, and Sun Pharmaceutical Industries, Inc. markets and sells generic drugs
14 throughout the United States and in particular within the State of Nevada, and therefore Sun
15 Pharmaceutical Industries Limited transacts business within the State of Nevada such that it has
16 engaged in systematic and continuous business contacts within the State of Nevada. In addition,
17 Sun Pharmaceutical Industries Limited is subject to personal jurisdiction in Nevada because, on
18 information and belief, it controls and dominates Sun Pharma Global FZE, Sun Pharma Global,
19 and Sun Pharmaceutical Industries, Inc. and therefore the activities of these companies in this
20 jurisdiction are attributed to Sun Pharmaceutical Industries Limited.

21 11. On information and belief, Sun Pharmaceutical Industries Limited (itself or
22 through its subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical
23 Industries, Inc.) markets its generic drug products to residents of the State of Nevada through its
24 website.

25 12. On information and belief, Sun Pharmaceutical Industries Limited (itself or
26 through its subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical
27 Industries, Inc.) offers its generic drug products for sale to residents of the State of Nevada on
28 third-party websites that Nevada residents can use to purchase Sun products for shipment to and

1 within the State of Nevada.

2 13. On information and belief, residents of the State of Nevada purchase generic drug
3 products from Sun Pharmaceutical Industries Limited (itself or through its subsidiaries Sun
4 Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical Industries, Inc.) in the State of
5 Nevada.

6 14. On information and belief, Sun Pharmaceutical Industries Limited (itself or
7 through its subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical
8 Industries, Inc.) receives revenue from the sales and marketing of its generic drug products in the
9 State of Nevada.

10 15. On information and belief, Sun Pharmaceutical Industries Limited (itself or
11 through its subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical
12 Industries, Inc.) uses sales representatives in the State of Nevada to promote the sales of Sun's
13 generic drugs throughout the State of Nevada.

14 16. On information and belief, Sun Pharmaceutical Industries Limited (itself or
15 through its subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical
16 Industries, Inc.) has attended trade shows in the State of Nevada for the purpose of promoting and
17 selling Sun's generic drug products.

18 17. On information and belief, Sun Pharmaceutical Industries Limited (itself or
19 through its subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical
20 Industries, Inc.) has several authorized distributors in the State of Nevada to distribute Sun's
21 generic drug products throughout the State of Nevada.

22 18. On information and belief, Sun Pharmaceutical Industries Limited (itself or
23 through its subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical
24 Industries, Inc.) plans to market and sell the product that is the subject of Sun's ANDA No. 20-
25 2318, if approved, in the State of Nevada as an alternative to Bayer's YAZ® product currently
26 being sold in the State of Nevada.

27 19. On information and belief, Sun Pharma Global is subject to personal jurisdiction in
28 the State of Nevada because, among other things, Sun Pharma Global, itself and through its

1 parent Sun Pharmaceutical Industries Limited, its wholly owned and operating subsidiary Sun
2 Pharma Global FZE or affiliated company Sun Pharmaceutical Industries, Inc. has purposely
3 availed itself of the benefits and protections of Nevada's laws such that it should reasonably
4 anticipate being haled into court here. On information and belief, Sun Pharma Global, itself and
5 through its parent Sun Pharmaceutical Industries Limited, its wholly owned and operating
6 subsidiary Sun Pharma Global FZE or affiliated company Sun Pharmaceutical Industries, Inc.
7 markets and sells generic drugs throughout the United States and in particular within the State of
8 Nevada, and therefore Sun Pharma Global transacts business within the State of Nevada such that
9 it has engaged in systematic and continuous business contacts within the State of Nevada. In
10 addition, Sun Pharma Global is subject to personal jurisdiction in Nevada because, on information
11 and belief, it controls and dominates Sun Pharma Global FZE and therefore the activities of this
12 company in this jurisdiction are attributed to Sun Pharma Global.

13 20. On information and belief, Sun Pharma Global (itself or through its parent Sun
14 Pharmaceutical Industries Limited, its wholly owned subsidiary Sun Pharma Global FZE or
15 affiliated company Sun Pharmaceutical Industries, Inc.) markets its generic drug products to
16 residents of the State of Nevada through its website.

17 21. On information and belief, Sun Pharma Global (itself or through its parent Sun
18 Pharmaceutical Industries Limited, its wholly owned subsidiary Sun Pharma Global FZE or
19 affiliated company Sun Pharmaceutical Industries, Inc.) offers its generic drug products for sale to
20 residents of the State of Nevada on third-party websites that Nevada residents can use to purchase
21 Sun products for shipment to and within the State of Nevada.

22 22. On information and belief, residents of the State of Nevada purchase generic drug
23 products from Sun Pharma Global (itself or through its parent Sun Pharmaceutical Industries
24 Limited, its wholly owned subsidiary Sun Pharma Global FZE or affiliated company Sun
25 Pharmaceutical Industries, Inc.) in the State of Nevada.

26 23. On information and belief, Sun Pharma Global (itself or through its parent Sun
27 Pharmaceutical Industries Limited, its wholly owned subsidiary Sun Pharma Global FZE or
28 affiliated company Sun Pharmaceutical Industries, Inc.) receives revenue from the sales and

1 marketing of its generic drug products in the State of Nevada.

2 24. On information and belief, Sun Pharma Global (itself or through its parent Sun
3 Pharmaceutical Industries Limited, its wholly owned subsidiary Sun Pharma Global FZE or
4 affiliated company Sun Pharmaceutical Industries, Inc.) uses sales representatives in the State of
5 Nevada to promote the sales of Sun's generic drugs throughout the State of Nevada.

6 25. On information and belief, Sun Pharma Global (itself or through its parent Sun
7 Pharmaceutical Industries Limited, its wholly owned subsidiary Sun Pharma Global FZE or
8 affiliated company Sun Pharmaceutical Industries, Inc.) has attended trade shows in the State of
9 Nevada for the purpose of promoting and selling Sun's generic drug products.

10 26. On information and belief, Sun Pharma Global (itself or through its parent Sun
11 Pharmaceutical Industries Limited, its wholly owned subsidiary Sun Pharma Global FZE or
12 affiliated company Sun Pharmaceutical Industries, Inc.) has several authorized distributors in the
13 State of Nevada to distribute Sun's generic drug products throughout the State of Nevada.

14 27. On information and belief, Sun Pharma Global (itself or through its parent Sun
15 Pharmaceutical Industries Limited, its wholly owned subsidiary Sun Pharma Global FZE or
16 affiliated company Sun Pharmaceutical Industries, Inc.) plans to market and sell the product that
17 is the subject of Sun's ANDA No. 20-2318, if approved, in the State of Nevada as an alternative
18 to Bayer's YAZ® product currently being sold in the State of Nevada.

19 28. On information and belief, Sun Pharma Global FZE is subject to personal
20 jurisdiction in the State of Nevada because, among other things, Sun Pharma Global FZE (itself
21 or through its parents Sun Pharmaceutical Industries Limited and Sun Pharma Global or its
22 affiliated company Sun Pharmaceutical Industries, Inc.) has purposely availed itself of the
23 benefits and protections of Nevada's laws such that it should reasonably anticipate being haled
24 into court here. On information and belief, Sun Pharma Global FZE (itself or through its parents
25 Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun
26 Pharmaceutical Industries, Inc.) markets and sells generic drugs throughout the United States and
27 in particular within the State of Nevada, and therefore Sun Pharma Global FZE transacts business
28 within the State of Nevada such that it has engaged in systematic and continuous business

1 contacts within the State of Nevada.

2 29. On information and belief, Sun Pharma Global FZE (itself or through its parents
3 Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun
4 Pharmaceutical Industries, Inc.) markets its generic drug products to residents of the State of
5 Nevada through Sun's website.

6 30. On information and belief, Sun Pharma Global FZE (itself or through its parents
7 Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun
8 Pharmaceutical Industries, Inc.) offers its generic drug products for sale to residents of the State
9 of Nevada on third-party websites that Nevada residents can use to purchase Sun products for
10 shipment to and within the State of Nevada.

11 31. On information and belief, residents of the State of Nevada purchase generic drug
12 products from Sun Pharma Global FZE (itself or from its parents Sun Pharmaceutical Industries
13 Limited and Sun Pharma Global or its affiliated company Sun Pharmaceutical Industries, Inc.) in
14 the State of Nevada.

15 32. On information and belief, Sun Pharma Global FZE (itself or through its parents
16 Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun
17 Pharmaceutical Industries, Inc.) receives revenue from the sales and marketing of its generic drug
18 products in the State of Nevada.

19 33. On information and belief, Sun Pharma Global FZE (itself or through its parents
20 Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun
21 Pharmaceutical Industries, Inc.) uses sales representatives in the State of Nevada to promote the
22 sales of Sun's generic drugs throughout the State of Nevada.

23 34. On information and belief, Sun Pharma Global FZE (itself or through its parents
24 Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun
25 Pharmaceutical Industries, Inc.) has attended trade shows in the State of Nevada for the purpose
26 of promoting and selling Sun's generic drug products.

27 35. On information and belief, Sun Pharma Global FZE (itself or through its parents
28 Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun

1 Pharmaceutical Industries, Inc.) has several authorized distributors in the State of Nevada to
2 distribute Sun's generic drug products throughout the State of Nevada.

3 36. On information and belief, Sun Pharma Global FZE (itself or through its parents
4 Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun
5 Pharmaceutical Industries, Inc.) plans to market and sell the product that is the subject of Sun's
6 ANDA No. 20-2318, if approved, in the State of Nevada as an alternative to Bayer's YAZ®
7 product currently being sold in the State of Nevada.

8 37. On information and belief, Sun Pharmaceutical Industries, Inc. is subject to
9 personal jurisdiction in the State of Nevada because, among other things, Sun Pharmaceutical
10 Industries, Inc. (itself or through its parent Sun Pharmaceutical Industries Limited or its affiliated
11 companies Sun Global Pharma or Sun Global Pharma FZE) has purposely availed itself of the
12 benefits and protections of Nevada's laws such that it should reasonably anticipate being haled
13 into court here. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through
14 its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma
15 or Sun Global Pharma FZE) markets and sells generic drugs throughout the United States and in
16 particular within the State of Nevada, and therefore Sun Pharmaceutical Industries, Inc. transacts
17 business within the State of Nevada such that it has engaged in systematic and continuous
18 business contacts within the State of Nevada.

19 38. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through
20 its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma
21 or Sun Global Pharma FZE) markets its generic drug products to residents of the State of Nevada
22 through Sun's website.

23 39. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through
24 its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma
25 or Sun Global Pharma FZE) offers its generic drug products for sale to residents of the State of
26 Nevada on third-party websites that Nevada residents can use to purchase Sun products for
27 shipment to and within the State of Nevada.

28 40. On information and belief, residents of the State of Nevada purchase generic drug

1 products from Sun Pharmaceutical Industries, Inc. (itself or through its parent Sun Pharmaceutical
2 Industries Limited or its affiliated companies Sun Global Pharma or Sun Global Pharma FZE) in
3 the State of Nevada.

4 41. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through
5 its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma
6 or Sun Global Pharma FZE) receives revenue from the sales and marketing of its generic drug
7 products in the State of Nevada.

8 42. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through
9 its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma
10 or Sun Global Pharma FZE) uses sales representatives in the State of Nevada to promote the sales
11 of Sun's generic drugs throughout the State of Nevada.

12 43. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through
13 its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma
14 or Sun Global Pharma FZE) has attended trade shows in the State of Nevada for the purpose of
15 promoting and selling Sun's generic drug products.

16 44. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through
17 its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma
18 or Sun Global Pharma FZE) has several authorized distributors in the State of Nevada to
19 distribute Sun's generic drug products throughout the State of Nevada.

20 45. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through
21 its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma
22 or Sun Global Pharma FZE) plans to market and sell the product that is the subject of Sun's
23 ANDA No. 20-2318, if approved, in the State of Nevada as an alternative to Bayer's YAZ®
24 product currently being sold in the State of Nevada.

25 46. Venue is proper under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

26 BACKGROUND

27 47. Bayer HealthCare is the holder of approved New Drug Application ("NDA") No.
28 21-676 for YAZ® tablets, which contain as active ingredients micronized drospirenone and

1 micronized 17 α -ethinylestradiol. The United States Food and Drug Administration (“FDA”) has
2 approved YAZ® tablets for the prevention of pregnancy in women and for the treatment of
3 moderate acne and the symptoms of premenstrual dysphoric disorder in women who elect to use
4 an oral contraceptive.

5 48. Bayer HealthCare sells YAZ® tablets in the United States as a 28-day oral
6 contraceptive regimen that contains 24 tablets comprising 3 mg of micronized drospirenone and
7 0.02 mg of micronized 17 α -ethinylestradiol plus 4 placebo tablets.

8 49. On information and belief, Sun submitted to the FDA ANDA No. 20-2318 under
9 the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture,
10 use, offer for sale, sale and/or importation of a generic version of Bayer’s YAZ® tablets.

11 50. On information and belief, the composition of the product that is the subject of
12 Sun’s ANDA contains 3 mg of drospirenone and 0.02 mg of ethinylestradiol in tablet form for
13 oral contraception in a human female (hereinafter “Sun’s YAZ® ANDA product”).

14 51. On information and belief, Sun’s ANDA seeks approval of a 28-day oral
15 contraceptive regimen that contains 24 tablets comprising 3 mg of drospirenone and 0.02 mg
16 17 α -ethinylestradiol plus 4 placebo tablets.

17 52. On information and belief, on November 29, 2010, Sun sent a Notice Letter to
18 Plaintiffs Bayer Schering and Bayer HealthCare, purporting to comply with the provisions of
19 21 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto.

20 PATENTS-IN-SUIT

21 53. The three patents-in-suit are United States Reissue Patent Nos. 37,564, 37,838, and
22 38,253.

23 54. United States Reissue Patent No. 37,564 (“the ’564 reissue patent”) issued on
24 February 26, 2002. Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their
25 application for this patent on February 15, 2000. Bayer Schering is the current owner of the ’564
26 reissue patent. Bayer attaches a true and correct copy of the ’564 reissue patent as Exhibit 1.

27 55. United States Reissue Patent No. 37,838 (“the ’838 reissue patent”) issued on
28 September 10, 2002. Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their

1 application for this patent on February 15, 2000. Bayer Schering is the current owner of the '838
2 reissue patent. Bayer attaches a true and correct copy of the '838 reissue patent as Exhibit 2.

3 56. United States Reissue Patent No. 38,253 ("the '253 reissue patent") issued on
4 September 16, 2003. Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their
5 application for this patent on February 25, 2002. Bayer Schering is the current owner of the '253
6 reissue patent. Bayer attaches a true and correct copy of the '253 reissue patent as Exhibit 3.

7
8 **COUNT ONE: CLAIM FOR PATENT INFRINGEMENT OF U.S. REISSUE
PATENT NO. 37,564**

9 57. Bayer incorporates paragraphs 1-56 of this Complaint as if fully set forth herein.

10 58. On information and belief, Sun's YAZ® ANDA product infringes one or more
11 claims of the '564 reissue patent.

12 59. The '564 reissue patent covers Bayer HealthCare's YAZ® tablets, and Bayer has
13 listed the '564 reissue patent for YAZ® in the FDA *Approved Drug Products and Therapeutic*
14 *Equivalence Evaluations* ("the Orange Book").

15 60. On information and belief, Sun submitted ANDA No. 20-2318 to the FDA for the
16 purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale
17 and/or importation of Sun's YAZ® ANDA product before the expiration of the '564 reissue
18 patent.

19 61. On information and belief, Sun made and included in ANDA No. 20-2318 a
20 certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '564 reissue
21 patent is invalid or will not be infringed by the manufacture, use, offer for sale, sale and/or
22 importation of Sun's YAZ® ANDA product.

23 62. By filing ANDA No. 20-2318 under 21 U.S.C. § 355(j) for the purpose of
24 obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or
25 importation of Sun's YAZ® ANDA product before the expiration of the '564 reissue patent, Sun
26 has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and
27 belief, the commercial manufacture, use, offer for sale, sale and/or importation of Sun's YAZ®
28 ANDA product will also infringe one or more claims of the '564 reissue patent.

63. Plaintiffs Bayer Schering and Bayer HealthCare are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to ANDA No. 20-2318 shall be a date which is not earlier than June 30, 2014, the current expiration date of the '564 reissue patent, or any later date of exclusivity to which Bayer becomes entitled. Bayer Schering and Bayer HealthCare are entitled to an award of damages and treble damages for any commercial sale or use of Sun's YAZ® ANDA product, and any act committed by Sun with respect to the subject matter claimed in the '564 reissue patent that is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

64. On information and belief, when Sun filed ANDA No. 20-2318, it was aware of the '564 reissue patent and was aware that the filing of ANDA No. 20-2318 with the request for its approval prior to the expiration of the '564 reissue patent constituted an act of infringement of the '564 reissue patent.

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**COUNT TWO: CLAIM FOR PATENT INFRINGEMENT OF U.S. REISSUE
PATENT NO. 37,838**

65. Bayer incorporates paragraphs 1-64 of this Complaint as if fully set forth herein.

66. On information and belief, Sun's YAZ® ANDA product infringes one or more claims of the '838 reissue patent.

67. The '838 reissue patent covers Bayer HealthCare's YAZ® tablets, and Bayer has listed the '838 reissue patent for YAZ® in the *FDA Approved Drug Products and Therapeutic Equivalence Evaluations* ("the Orange Book").

68. On information and belief, Sun submitted ANDA No. 20-2318 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Sun's YAZ® ANDA product before the expiration of the '838 reissue patent.

69. On information and belief, Sun made and included in ANDA No. 20-2318 a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '838 reissue

1 patent is invalid or will not be infringed by the manufacture, use, offer for sale, sale and/or
2 importation of Sun's YAZ® ANDA product.

3 70. By filing ANDA No. 20-2318 under 21 U.S.C. § 355(j) for the purpose of
4 obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or
5 importation of Sun's YAZ® ANDA product before the expiration of the '838 reissue patent, Sun
6 has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and
7 belief, the commercial manufacture, use, offer for sale, sale and/or importation of Sun's YAZ®
8 ANDA product will also infringe one or more claims of the '838 reissue patent.

9 71. Plaintiffs Bayer Schering and Bayer HealthCare are entitled to the relief provided
10 by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval
11 relating to ANDA No. 20-2318 shall be a date which is not earlier than June 30, 2014, the current
12 expiration date of the '838 reissue patent, or any later date of exclusivity to which Bayer becomes
13 entitled. Further, Bayer Schering and Bayer HealthCare are entitled to an award of damages and
14 treble damages for any commercial sale or use of Sun's YAZ® ANDA product, and any act
15 committed by Sun with respect to the subject matter claimed in the '838 reissue patent that is not
16 within the limited exclusions of 35 U.S.C. § 271(e)(1).

17 72. On information and belief, when Sun filed ANDA No. 20-2318, it was aware of
18 the '838 reissue patent and was aware that the filing of ANDA No. 20-2318 with the request for
19 its approval prior to the expiration of the '838 reissue patent constituted an act of infringement of
20 the '838 reissue patent.

21 **COUNT THREE: CLAIM FOR PATENT INFRINGEMENT OF U.S.**
22 **REISSUE PATENT NO. 38,253**

23 73. Bayer incorporates paragraphs 1-72 of this Complaint as if fully set forth herein.

24 74. On information and belief, Sun's YAZ® ANDA product infringes one or more
25 claims of the '253 reissue patent.

26 75. The '253 reissue patent covers Bayer HealthCare's YAZ® tablets, and Bayer has
27 listed the '253 reissue patent for YAZ® in the FDA *Approved Drug Products and Therapeutic*
28 *Equivalence Evaluations* ("the Orange Book").

1 76. On information and belief, Sun submitted ANDA No. 20-2318 to the FDA for the
2 purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale
3 and/or importation of Sun's YAZ® ANDA product before the expiration of the '253 reissue
4 patent.

5 77. On information and belief, Sun made and included in ANDA No. 20-2318 a
6 certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '253 reissue
7 patent is invalid or will not be infringed by the manufacture, use, offer for sale, sale and/or
8 importation of Sun's YAZ® ANDA product.

9 78. By filing ANDA No. 20-2318 under 21 U.S.C. § 355(j) for the purpose of
10 obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or
11 importation of Sun's YAZ® ANDA product before the expiration of the '253 reissue patent, Sun
12 has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and
13 belief, the commercial manufacture, use, offer for sale, sale and/or importation of Sun's YAZ®
14 ANDA product will also infringe one or more claims of the '253 reissue patent.

15 79. Plaintiffs Bayer Schering and Bayer HealthCare are entitled to the relief provided
16 by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval
17 relating to ANDA No. 20-2318 shall be a date which is not earlier than June 30, 2014, the current
18 expiration date of the '253 reissue patent, or any later date of exclusivity to which Bayer becomes
19 entitled. Further, Bayer Schering and Bayer HealthCare are entitled to an award of damages and
20 treble damages for any commercial sale or use of Sun's YAZ® ANDA product, and any act
21 committed by Sun with respect to the subject matter claimed in the '253 reissue patent that is not
22 within the limited exclusions of 35 U.S.C. § 271(e)(1).

23 80. On information and belief, when Sun filed ANDA No. 20-2318, it was aware of
24 the '253 reissue patent and was aware that the filing of its ANDA with the request for its approval
25 prior to the expiration of the '253 reissue patent constituted an act of infringement of the '253
26 reissue patent.

27 **PRAYER FOR RELIEF**

28 **WHEREFORE** Bayer respectfully requests the following relief:

1 Dated: January 11, 2011

Respectfully submitted,

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3 /s/

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(*pro hac vice* applications to be filed)

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